



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/614,653	07/07/2003	Andrew Kim	ACK006	7515
James W. Chang P.O. Box 1497 Loma Linda, CA 92354			EXAMINER BACHMAN, LINDSEY MICHELLE	
			ART UNIT 3734	PAPER NUMBER
			MAIL DATE 05/27/2009	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/614,653

Applicant(s)

KIM, ANDREW

Examiner

LINDSEY BACHMAN

Art Unit

3734

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 January 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5-11 and 15-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5-11 and 15-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SI/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

This Office Action is in response to Applicant's amendment filed 30 January 2009.

Claim Objections

Applicant is reminded to please identify all changes to the claims with underlines, strikethroughs, etc. as appropriate, in accordance with 37 CFR 1.121(c)(2). Claim 5 was not properly identified in the amendment filed 30 January 2009.

Response to Arguments

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5 recites the limitation "said syringe barrel" on line 14. There is insufficient antecedent basis for this limitation in the claim.

Claim 5 recites the limitation "a connector" on line 14. This limitation was previously presented on line 4 and it is unclear if Applicant is claiming a different connector or referring back to the connector on line 4.

Claims 6 and 7 recite the limitation "said curved configuration" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim 5-7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gray (US Patent 7,077,826) in view of Bittner et al. (US Patent 5,515,871).

Claims 5, 6, 7: Gray discloses a syringe (shown in Figures 1 and 2) that contains a barrel (101) and a connector (105H) for detachably mounting to a needle (column 25, lines 25-28). The chamber has the capacity to receive a suture and fluid. The suction device further contains a plunger (103) mounted in the chamber (see Figure 1). There are no components mounted inside the chamber between the plunger and the outlet of the chamber (see Figure 1). The Gray device further contains an elongated needle (105) that contains a lumen and is capable of receiving a suture. Gray does not teach that the needle has a rounded trailing edge.

Bittner'871 teaches a needle intended for use with syringes (column 1, lines 10-15) that contains a sharp leading edge around a rounded trailing edge (44') (see Figures 4a, 4b) for the purpose of preventing the needle lumen from becoming blocked when

placed into tissue and creating syringe abscesses (column 1, lines 15-32). It would have been obvious to one of ordinary skill in the art to modify the needle taught by Gray'826 with the needle having a rounded trailing edge and sharp leading edge taught by Bittner'871 so that it too has this advantage.

Claims 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gray'826 in view of Bittner'871, as applied to Claim 5, further in view of Sapienza (US Patent 5,376,081).

Claim 7: Gray in view of Bittner'871 teaches the limitations of Claim 8 except for a stiffening cover over the needle.

Sapienza teaches that it is old and well known to provide a cover (10) over the needle (9) on a syringe (Figure 1) in order to stiffen it and limit its tendency to bend (column 3, line 56 to column 4, line 1). It would have been obvious to modify the device of Gray'826 so that it too has this advantage.

Claim 5 and 9-11 are rejected under Casperi et al. (US Patent 4,890,615) in view of Weng (US patent 5,569,270) in view of Bittner'871.

Claim 5, 9, 11: Casperi teaches the use of a suturing device with a pair of jaws (34, 44), a proximal lever to operate the jaws (24, 26), and a lumen (36 is a tubular member) extending from the proximal end to distal end for passage of a needle (56). The needle expels the suture from its tip (column 5, lines 13-17). Casperi does not teach that the suture distributor is a syringe or that the needle has a rounded trailing edge.

Weng'270 teaches a suturing device that includes an elongate needle (46) having a lumen extending from the proximal end to the distal end that is capable of passing a suture (column 2, lines 45-60). The device also contains a barrel (24, column 4, lines 44-46) and plunger (32) and a connector (58). Suture material is introduced into the needle (column 2, lines 54-56 and column 3, lines 55-63). Liquid fills the barrel, the needle is passed through the tissue to be sutured and the suture is expelled with the force of the liquid flow (column 2, lines 45-60). Weng'270 discloses a stiffening cover (60) that covers most of the needle (see Figure 1). It would have been obvious to modify the suture distributor taught by Caspari with the suture distributor taught by Weng'270 because it would be obvious to apply a known technique to a known device ready for improvement in order to yield predictable results.

Bittner'871 teaches a needle intended for use with syringes (column 1, lines 10-15) that contains a sharp leading edge around a rounded trailing edge (44') (see Figures 4a, 4b) for the purpose of preventing the needle lumen from becoming blocked when placed into tissue and creating syringe abscesses (column 1, lines 15-32). It would have been obvious to one of ordinary skill in the art to modify the needle taught by Caspari with the needle having a rounded trailing edge and sharp leading edge taught by Bittner'871 so that it too has this advantage.

Claim 10: Caspari in view of Weng does not disclose that the needle has a particular shape at the distal end. However, it is old and well known to modify the shape of needles to aid in accessing a particular region of the body, especially if the region would be more easily accessed with a needle of a different shape.

Claims 15-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weng (US Patent 5,569,270) in view of Baber (US Patent 5,152,769).

Claim 15, 17, 18: Weng'270 teaches a method of suturing with a suturing device that includes an elongate curved needle (46) having a lumen extending from the proximal end to the distal end that is capable of passing a suture (column 2, lines 45-60). The device also contains a barrel (24, column 4, lines 44-46) and plunger (32) and a connector (58). Suture material is introduced into the needle (column 2, lines 54-56 and column 3, lines 55-63). Liquid fills the barrel, the needle is passed through the tissue to be sutured and the suture is expelled with the force of the liquid flow (column 2, lines 45-60). Weng'270 discloses a stiffening cover (60) that covers most of the needle (see Figure 1).

Weng'270 does not explicitly disclose folding the suture over the trailing end of the needle. However, it since the needle, not the suture, is penetrating the tissue because it is configured with rigidity and sharpness in order penetrate tissue, it is clear that during the suturing procedure, the suture will be folded back over the needle as the needle passes through tissue. Regarding whether the needle is folded over the front tip or trail portion of the needle, this is an obvious since there is a finite number of predictable potential solutions: the suture must be folded over either the leading or trailing portion of the needle. Baber'769 shows an example of a suture (30) that is folded back over a trailing edge (15) of the needle opening (see Figures 9 and 10). In this situation, a person of ordinary skill in the art would have pursued the known potential solutions with a reasonable expectation of success. If one of these solutions

leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense.

Claim 16: Weng'270 does not disclose introducing the suture into the barrel with drawing liquid into the barrel at the same time as the suture. However, it is old and well known to draw things into syringes via the suction provided by the plunger. It would be obvious to one of ordinary skill in the art to try drawing the suture into the syringe because choosing from a finite number of identified predictable solutions would have a reasonable expectation of success. Further, it is old and well known to apply a known technique to a known device to yield predictable results.

Claims 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weng'270 in view of Baber'769, as applied to Claim 15, in further view of Caspari.

Claim 19, 20: Weng'270 teaches the limitations of Claim 19 and 20 except for a pair of jaws directing the needle and suture.

Caspari teaches the use of a suturing device with a pair of jaws (34, 44), a proximal lever to operate the jaws (24, 26), and a lumen (36 is a tubular member) extending from the proximal end to distal end for passage of a needle (56). The needle expels the suture from its tip (column 5, lines 13-17). It would have been obvious to modify the method of Weng'270 by combining Weng'270's tool with Caspari in order to increase the amount of control over the suturing operation and also increase the functionality of the device.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LINDSEY BACHMAN whose telephone number is (571)272-6208. The examiner can normally be reached on Monday to Thursday 7:30 am to 5 pm, and alternating Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/L. B./
Examiner, Art Unit 3734

/Todd E Manahan/
Supervisory Patent Examiner, Art Unit 3734